EXHIBIT F

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
Medicare Appeals Council
Docket No. M-19-1748

J.O., Appellant
ALJ Appeal No. 1-8237389961

DECISION

The Medicare Appeals Council (Council) has decided, on its own motion, to review the Administrative Law Judge (ALJ)'s decision dated March 14, 2019, because there is an error of law material to the outcome of the claims. 42 C.F.R. § 405.1110. Relevant here, the ALJ found that sensors (HCPCS code A9276) for a continuous glucose monitoring (CGM) system, furnished to the beneficiary-appellant on June 5, 2018, an external transmitter (HCPCS code A9277) for a CGM system, furnished on March 14, 2018, and waterproof tape (HCPCS code A4452) for use with the CGM system, furnished on April 18, 2018, were covered by Medicare.[1]

By memorandum dated May 7, 2019, the Centers for Medicare & Medicaid Services (CMS) has asked the Council to review the ALJ's decision.42 C.F.R. § 405.1110. The Council limits its consideration of the ALJ's decision to the specific exceptions raised by CMS. We enter the CMS referral memorandum into the record as Exhibit (Exh.) MAC-1. CMS sent a copy of its referral memorandum to the appellant, and the appellant, through his family representative, has filed a response, which the Council enters into the record as Exh. MAC-2.

After carefully considering the record that was before the ALJ, as well as the CMS memorandum and the appellant's exceptions, we find that the items at issue are not covered by Medicare. Therefore, we reverse the ALJ's decision.

LEGAL BACKGROUND

Medicare is a defined benefits program. Section 1832(a) of the Social Security Act (Act) provides that benefits under Medicare Part B include "medical and other health services."

[1] The Centers for Medicare & Medicaid Services (CMS), the federal agency that administers the Medicare program, has established a coding system for screening, processing, identifying, and paying Medicare claims named the Healthcare Common Procedure Coding System (HCPCS). *See* 42 C.F.R. §§ 414.2, 414.40. The HCPCS incorporates codes developed by the American Medical Association, Current Procedure Terminology (CPT) codes, to identify and describe medical services and items.

Section 1861(s)(6) of the Act defines "medical and other health services" as including durable medical equipment (DME). Section 1861(n) of the Act lists certain items that are classified as DME. However, by its own terms, section 1861(n) is not an exhaustive list of those items that qualify as DME. Thus, the fact that an item is not listed in section 1861(n) does not necessarily mean that it is not DME.

The regulations define DME as equipment that:

- can withstand repeated use;
- has an expected life of at least three years;
- *is primarily and customarily used to serve a medical purpose*;
- generally is not useful to an individual in the absence of an illness or injury; and
- is appropriate for use in the home.

42 C.F.R. § 414.202. A device or system which does not comply with all the terms of this definition does not fall within the statutory DME benefit of the Medicare program.

To receive Medicare coverage, a device must first meet the definition of DME, and must also be medically "reasonable and necessary" for the particular beneficiary and in fact be used in the beneficiary's home. Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, Ch. 15, § 110. A claim for a device or system which meets the definition of DME would thus only be covered by Medicare when used by a beneficiary for medical purposes.

The CMS Administrator from time to time issues Rulings that serve as precedent final opinions and official statements of agency policy and interpretation. On January 12, 2017, the CMS Administrator issued a Ruling addressing whether any CGM systems constituted DME. The Ruling[2] states:

> The FDA recently approved expanding the indications of one CGM product to include replacement of blood glucose monitors for diabetes treatment decisions. This Ruling addresses whether 'therapeutic' CGMs, which provide information that can be used to make diabetes treatment decisions meet the definition of DME. For the purpose of this Ruling, all CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as 'non-therapeutic' CGMs.

CMS Ruling 1682-R (2017 Ruling) at 7. The 2017 Ruling further states that such "therapeutic" CGM systems will be considered DME if the *CGM system is* "approved by

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[2] https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf (last visited July 10, 2019).

the FDA *for use in place of a blood monitor for making diabetes treatment decisions*[;]" generally is not useful to the individual in the absence of an illness or injury; is appropriate for use in the home; and includes a durable component. 2017 Ruling at 13-14 (emphasis added). In all other cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM is not considered DME.

CMS issues national coverage determinations (NCDs) to specifically address certain items and services. "An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a). "NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered) under § 1862(a)(1) of the Act or other applicable provisions of the Act." Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 13, § 13.1.1. NCDs are binding on all contractors, ALJs, and the Council. 42 C.F.R. § 405.1060(a)(4).

No NCD addresses whether CGM devices or systems qualify as DME or are covered under Medicare. By contrast, the Act has explicitly included home blood glucose monitors as DME and a current NCD spells out the conditions and limitations under which such monitors and associated supplies may be covered. Act § 1861(n); Medicare NCD Manual, CMS Pub. 100-03, § 40.2 (NCD 40.2). CGM devices do not test or monitor blood glucose, but rather monitor interstitial fluid for glucose values, a critical distinction we discuss in more detail later.

A Medicare administrative contractor may issue a local coverage determination (LCD) that "is a decision . . . whether to cover a particular item or service on a [contractor]-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the [Act] (i.e., a determination as to whether the item or service is reasonable and necessary.)" MPIM, Ch. 13, § 13.1.3. LCDs speak only to whether and in which circumstances an item or service meets the coverage requirement of being medically reasonable and necessary for beneficiaries' conditions.[3] Information that is not related to reasonableness and necessity criteria, including whether an item falls within a benefit category or is governed by a statutory exclusion, is published through an associated policy article. *Id.* LCDs thus would not address whether a device or system falls within the Medicare definition of DME at all, as opposed to whether or when an item of DME is covered under Medicare for use by a beneficiary. ALJs and the Council are not bound by, but are required to give "substantial deference" to, applicable LCDs and other CMS program guidance including program memoranda and manual instructions. 42 C.F.R. § 405.1062(a).

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[3] An LCD may list relevant HCPCS codes to identify products, supplies, and services, including items of DME, being addressed. The HCPCS was developed by CMS for processing, screening, identifying, and paying Medicare claims. 42 C.F.R. § 414.40. HCPCS is not a methodology or system for making coverage or payment determinations and the development of codes is independent of the coverage determination process. The mere existence of a code for an item or service does not constitute a determination regarding medical necessity, coverage or payment.

The relevant DME contractor published an LCD relating to glucose monitors applicable during the dates of service at issue: L33822 (effective Jan. 12, 2017).[4] The LCD provides that home blood glucose monitors will be considered medically reasonable and necessary for a beneficiary only if the beneficiary has diabetes and is trained to use the home monitor. The LCD also specifies that payment for any glucose monitor will be denied as not medically reasonable and necessary if those two "basic coverage criteria" are not present.

The LCD referred to an associated policy article which contained non-medical necessity provisions applicable to glucose monitors. That policy article states:

> Effective for claims with dates of service on or after January 12, 2017, Medicare covers therapeutic CGM devices under the DME benefit. CGM devices covered by Medicare are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit).

Policy Article A52464 (effective Jan. 12, 2017).

BACKGROUND AND PROCEDURAL HISTORY

1. The CGM at issue

In order to manage diabetes, individuals need to test their levels of blood glucose at varying intervals and determine what treatment in terms of diet and/or insulin is appropriate. For those who need to test frequently, home blood glucose monitors may "enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment." NCD 40.2. These meters use blood drops placed by the patient on specially treated reagent strips to measure color changes and report blood glucose levels. *Id.*

A CGM does not measure blood glucose at all; rather, it estimates, on a continuous basis, the level of glucose in "interstitial" fluid. A CGM has three basic components: a disposable sensor, placed under the skin, that generates an electrical signal in response to the amount of interstitial glucose present and converts that signal into a glucose measurement; a transmitter to which the sensor's information is relayed; and a receiver (or monitor) that is wirelessly connected to the transmitter and receives the interstitial glucose measurement from the transmitter and displays it to the user. If the glucose levels

[4] Active LCDs are available at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx; retired LCDs are available at https://localcoverage.cms.gov/mcd_archive/ (both last visited July 10, 2019). Associated policy articles can be accessed from the same pages.

are high or low, depending on the brand/model, a user may be required to confirm those levels with a fingerstick before taking appropriate action.

Individuals who face daily challenges in managing glycemic levels and trying to avoid hypoglycemic and hyperglycemic episodes may benefit from the use of continuous glucose monitoring. Because continuous access to the blood is impractical, CGMs may provide such individuals with notice to test when levels appear problematic, as well as compiling data on glucose levels over time. However, until recently (as explained later in relation to the 2017 Ruling), treatment actions could not be based on CGM readings without direct blood testing.

2. The appellant's claim

The appellant is a type 1 diabetic who has hypoglycemic unawareness. Exh. 2 at 45. To manage his condition, the appellant uses a Medtronic MiniMed 670G system. *Id.* at 44.

At issue here is the appellant's claim for Medicare coverage of CGM sensors, a CGM transmitter and waterproof tape for use with his MiniMed. The Medicare contractor denied coverage for the sensors and the transmitter, initially and on redetermination, finding that "CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit)." Exh. 1 at 30. The waterproof tape was denied because a detailed written order and medical documentation was not submitted after requested. *Id.* at 24. On reconsideration, the Qualified Independent Contractor (QIC) upheld the coverage denial but indicated the reasons for denial was that an order for the items was not submitted for review. *Id.* at 4-5. Contrary to the contractor, the QIC held the supplier financially responsible for the non-covered charges. *Id.* at 5, 30.

3. The ALJ decision

Following a hearing in which the appellant and his family representative participated, the ALJ issued a fully favorable decision, finding that the items at issue were covered. Hearing Recording; ALJ Decision (Dec.). The ALJ found that the record now contains a physician signed and dated order for the items at issue. Dec. at 3. The ALJ also noted that the physician notes establish that the appellant is diagnosed with diabetes and chronic kidney disease, for which he underwent a kidney transplant. *Id.* In an effort to protect his kidney, the appellant is using a pump that was covered by Medicare, and the items at issue work with this pump. *Id.*

4. CMS's referral

In its referral memorandum, CMS asserts that the ALJ erred as a matter of law by not considering relevant requirements in the applicable 2017 Ruling and Medicare regulatory provisions regarding DME coverage. Exh. MAC-1 at 2. CMS notes that on redetermination, the contractor denied the items on the ground that "CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit)." *Id.* CMS asserts the ALJ erred as a matter of law by not addressing all the issues for the claims brought out in the redetermination that were not decided in the party's favor, as required by 42 C.F.R. § 405.132(a). *Id.*

CMS explains that under the 2017 Ruling, Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors. *Id.* at 2, 9 *citing* 2017 Ruling at 6-7, 15. The 2017 Ruling further explains that a CGM system may be eligible for Medicare coverage under the DME benefit when the system qualifies as a therapeutic CGM that meets the definition of DME. *Id.* at 8. The Ruling describes a therapeutic CGM system as one that was "designed and approved to replace a blood glucose monitor currently classified as DME under the Medicare program" and emphasized that the FDA must have approved the CGM "for use in place of a blood glucose monitor for making diabetes treatment decisions." *Id.* at 9-10. The 2017 Ruling indicated that only one CGM system had been approved as therapeutic as of its effective date of January 12, 2017, which CMS notes is the Dexcom G5. *Id.* at 9 n.5. CMS asserts that pursuant to 42 C.F.R. § 405.1063(b), CMS Rulings are binding on ALJs, and the ALJ erred as a matter of law by not considering the definition of a therapeutic CGM. *Id.* at 2, 8.

5. The appellant's exceptions

The appellant responded to the CMS referral, in pertinent part, as follows:

> I got letters from [the beneficiary's] primary care [doctor], his endocrinologist and his nephrologist saying it was medically necessary for this equipment. This does not replace what he is doing its just another tool to help manage his diabetes. We are trying to save his transplanted kidney. The [doctors] say keeping his blood sugars in range will help save the kidney. They believe uncontrolled blood sugar is why his own kidneys failed. He is considered a brittle diabetic. This product has helped to lower his A1C from over 10 to 7.1 and his blood sugar are in range over 70% of the time. This is a great improvement in controlling his diabetes. He still checks his blood sugars 4 or more times a day. We are not asking just because. We believe that this product will save his kidney for several

> years. I gathered all the [doctors] letters, progress reports and even made Minimed give me a copy of the original physician order.

Exh. MAC-2.

DISCUSSION

As explained below, we agree with CMS that the ALJ made errors of law material to the outcome of the claims. The ALJ failed to address the basis for the denial of the items at the redetermination level and apply the definition of a therapeutic CGM as set forth in the 2017 Ruling.

1. The determination of whether a device meets the definition of DME depends on the nature and purpose of the device, not the individual beneficiary's usage or clinical condition.

The appellant has emphasized throughout his appeal that the use of this CGM is reasonable and necessary for his medical condition, specifically as a type 1 diabetic with a history of uncontrolled blood sugar levels. The appellant's individual medical condition, however, is not at issue in this case. Before any question can arise of whether an item of DME may be reasonable and necessary for medical treatment under particular conditions, or whether an individual beneficiary's medical condition has been shown to meet those conditions, a particular device must meet the definition of DME.

Neither CMS in its referral, nor the Council in this decision, questions the appellant's medical condition, the judgment of his doctors, or the utility of the CGM to him. CMS argues, however, that the particular device which the appellant used during the date at issue is not DME and therefore does not fall within a Medicare-covered benefit category. In other words, CMS's position is, in essence, that classifying a device as DME (or not DME) has to do with its primary function in medical treatment, not any individual's use of the device. We agree.

The determination of whether an item falls within the definition of a statutory benefit category is fundamental to the nature of Medicare as a defined benefit program and its resolution cannot vary from one beneficiary to another. The benefits available under Medicare are defined on a program-wide basis. By contrast, an item or service that falls within one of the defined benefits may or may not be reasonable and necessary to treat a particular beneficiary's clinical condition, a question often briefly summarized as "medical necessity." LCDs, as explained earlier, are issued by contractors to help clarify what circumstances and clinical conditions demonstrate medical necessity for a covered benefit. Before a device like a CGM system can be the subject of an LCD at all, however, it must fall in a defined benefit category.

The focus of our analysis, therefore, must be not on how this beneficiary used the device, but on whether the device met all the definitional requirements of DME (the only statutory benefit category under which the appellant sought to claim coverage).

2. CMS has consistently interpreted the definition of DME as excluding CGMs not approved for therapeutic use.

We begin our analysis with the principle underlying CMS's treatment of CGMs, i.e., that, DME must be "primarily and customarily used to serve a medical purpose." 42 C.F.R § 410.202. CMS has concluded that some devices that may be useful to patients, and may provide reassurance or guidance or backup in various ways, may nevertheless not constitute DME serving a medical purpose. The MBPM provides some examples of equipment that is "presumptively nonmedical" such as equipment that serves "comfort or convenience functions," "physical fitness equipment (such as an exercycle)," or "precautionary-type equipment (such as preset portable oxygen units)." MBPM, Ch. 15, § 110.1(B)(2).[5] Such equipment is not DME even if it may have "some remote medically related use." *Id.*; *see also* NCD 280.1, explaining that preset (as opposed to adjustable) oxygen units are not DME because they are "precautionary equipment; essentially not therapeutic in nature."

Where regulatory language is subject to more than one interpretation, the agency invested with expertise in the subject matter is entitled to apply a reasonable reading, so long as it is a permissible construction of the statutory regime. *See, e.g., Select Specialty Hosp. of Atlanta v. Thompson,* 292 F.Supp.2d 57, 64 (D.D.C. 2003). In *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, the Supreme Court established that, if Congress has not "'directly spoken to the precise question at issue,'" then courts "must defer to a 'permissible' construction of the statute by the agency. *Chevron,* 467 U.S. 837, 843 (1984).

Such deference is particularly appropriate where the statutory and regulatory scheme most depends on agency expertise. As the District Court in Maryland has explained, "deference to the Secretary's interpretations of Medicare regulations is 'all the more warranted,' because Medicare 'is a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Almy v. Sebelius*, 749 F.Supp.2d 315, 324 (D. Md. 2010) (quoting *Dist. Mem'l Hosp. of Southwestern N.C. v. Thompson*, 364 F.3d 513, 518 (4th Cir.2004); *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)). "Courts consistently defer to the Secretary in recognition of her broad statutory authority over Medicare coverage matters . . . ." *Almy* at 324 n.2 (citing *Heckler v. Ringer*, 466 U.S. 602, 617 (1984)).

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[5] Other devices are identified in the MBPM as presumptively medical, including respirators, wheelchairs, and hospital beds. *Id.* at § 110.1(B)(1). In other cases, information may need to be developed to determine into which category a device falls. *Id.* at §110.1.

We note that at least two courts appear to have substituted an interpretation of the phrase "primarily and customarily used to serve a medical purpose" as merely meaning that a device does not have an obvious purpose that is unrelated to health. *See, e.g., Whitcomb v. Hargan*, Civ. No. 17-CV-14, slip. op. at 11 (October 26, 2017) (DME definition is "clear on its face" in that a "device's primary and customary purpose must be medical as opposed to non-medical."); *Bloom v. Azar*, Civ. No. 5:16-CV-121, slip. op. at 19 (January 29, 2018). We disagree. If this requirement merely meant that DME devices must have health-related uses, there would be no point to the further regulatory requirement that a device "generally is not useful to an individual in the absence of an illness or injury." 42 C.F.R. § 414.202. Regulatory language should be read in a manner that gives meaning and effect to all its terms. We conclude that CMS reasonably and within its authority interpreted the regulatory definition of DME to mean that CGM devices must essentially serve or add to therapeutic measures rather than merely be of some medical or health-related use.

We also note that at least one court takes issue with the characterization of CGMs as "precautionary" devices. *See Lewis v. Azar*, Civ. No. 15-13530, slip. op. at 8-9 (April 5, 2018). However, we note that CMS has expressed a consistent interpretation of the definition of DME as limited to those CGM devices which are suitable for direct determination of treatment actions. That interpretation was embodied in policy articles explaining that CGMs (like the kind the appellant used on the date of service) were not DME because they were "precautionary." While "precautionary" may be a less than felicitous term in this context, the meaning is not unreasonable. Oxygen units, like glucose monitors, are unlikely to be used in the absence of disease. Preset portable oxygen units may provide additional mobility and convenience which may, in some instances, be very important to a patient, but they do not add any treatment modality or function because they cannot be adjusted to respond to treatment needs. CGM systems like the one the appellant was using may provide information, including alerts, about blood sugar fluctuations, but they similarly do not add any treatment modality or function so long as the patient is required to return to blood glucose measures to make treatment decisions. Where an individual must still use another device to accomplish the medical purpose at issue (i.e., measuring the glucose in the individual's blood), the device is essentially used as an additional precaution, but not for the primary medical purpose.

3. CMS has interpreted the definition of DME as including CGMs approved for therapeutic use following issuance of CMS Ruling 1682-R.

However, effective January 12, 2017, CMS published Ruling 1682-R, which explains in detail Medicare's coverage policy for CGMs and ancillary equipment. The Ruling states:

> Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood

> glucose monitors. In our view, such devices are not used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, and therefore, have not been covered under Medicare because they are not considered to serve the medical purpose of making diabetes treatment decisions. In addition, CMS has viewed the nondurable sensors that measure the patient's glucose level as performing the medically necessary function of the system, and therefore, the system as a whole has not been regarded as durable equipment. This Ruling applies to certain CGMs furnished on or after the effective date of the Ruling.
>
> The FDA recently approved expanding the indications of one CGM product to include replacement of blood glucose monitors for diabetes treatment decisions. This Ruling addresses whether 'therapeutic' CGMs, which provide information that can be used to make diabetes treatment decisions meet the definition of DME. For the purpose of this Ruling, all CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as 'non-therapeutic' CGMs.

2017 Ruling at 7. We, like the ALJs, are bound by CMS Rulings. 42 C.F.R. § 405.1063(b).

In this case, the ALJ did not address whether the CGM at issue is a therapeutic CGM. Dec. We agree with CMS that the ALJ erred by not considering this when the 2017 Ruling was the basis for denial of the items on redetermination. *See* Exh. MAC-1 at 2. The 2017 Ruling states that "therapeutic" CGM systems will be considered DME if the CGM system is "approved by the FDA for use in place of a blood monitor for making diabetes treatment decisions[;]" generally is not useful to the individual in the absence of an illness or injury; is appropriate for use in the home; and includes a durable component. 2017 Ruling at 13-14 (emphasis added). The FDA has not approved the appellant's CGM system, a MiniMed, as a replacement for a blood glucose monitor. Thus, the CGM system at issue here is not DME. As a result, the CGM sensors and CGM transmitter, which are components of the CGM system, are not covered. As a supply to be used with the non-covered CGM system, the waterproof tape is also not covered. Accordingly, we reverse the ALJ's decision.

Financial Responsibility

We note that section 1879 of the Act limits the liability of a beneficiary in certain cases where coverage for an item or service is denied under section 1862(a)(1)(A) of the Act. However, in this case, coverage is denied because the CGM system at issue does not meet the definition of DME set forth in section 1861(n) of the Act, or the item is a supply

to be used with non-covered items. Therefore, section 1879's limitation on liability provisions do not apply in this case. *See* Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 30, § 20.2.2 (Section 1879 does not apply to "technical denials," such as cases where an item does not meet the definition of DME.). Accordingly, nothing in section 1879 of the Act precludes the supplier from billing the appellant for the non-covered items in this case.

DECISION

For the above reasons, the Council concludes that the CGM sensors (A9276) furnished on June 5, 2018, the CGM transmitter (A9277) furnished on March 14, 2018, and the waterproof tape (A4452) furnished on April 18, 2018, are not covered by Medicare. The Council reverses the ALJ's decision.

MEDICARE APPEALS COUNCIL

Debbie K. Nobleman
Administrative Appeals Judge

Constance B. Tobias
Chair, Departmental Appeals Board

Date: JUL 23 2019